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Attorney Docket No. B45308

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Morales, *et al.* 15 March 2005  
Int'l Serial No.: PCT/EP03/06094 Art Unit: unknown  
Int'l Filing Date: 10 June 2003 Examiner: unknown  
For: VACCINE COMPRISING MIXTURES OF MULTIVALENT  
MENINGOCOCCAL OUTER MEMBRANE VESICLES

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATUS INQUIRY

Sirs:

Applicants spoke with Debbie of the PCT Help Desk on 15 March 2005. Debbie was unable to retrieve any record of submission by international application number or attorney docket number. Enclosed, please find a copy of the submission to the USPTO filed 13 December 2004, the return express mail receipt, and the returned post card date stamped by the PCT/PTO.

Applicants have received no further correspondence or communications from the Commissioner of Patents concerning this case.

Applicant requests the current status of the application.

Respectfully submitted,

Jason C. Fedon

Jason C. Fedon  
Agent for Applicants

Registration No. 48,138

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04/06/2005 CSM001 00000002 192570 10529064  
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DOCKET No. B45308 Date Mailed 13 Dec 04 Atty/Secy JF/AmcMAILING: ~~CERTIFICATE~~ EXPRESS MAIL # EV608165276U.S. Serial No.: Unknown Filing Date: herewith  
Int'l App. No.: PCT/EP03/06094 Int'l Filing Date: 10 June 2003

## RECEIPT IS ACKNOWLEDGED FOR THE FOLLOWING:

- ☐ Appln. Trans. (+ 1 copy) for: ☐ Provisional ☐ CIP ☐ Statement to Support Filing  
☐ Utility/Continuation ☐ CPA ☐ RCE ☐ Divisional ☐ Copy of Notice to Comply  
☐ Specification      pages ☒ Abstract 1 pgs ☐ Diskette ☐ Paper Seq. Listing  
☐ Dec. & Power of Atty      pages (      ) ☐ Appeal Brief      pages  
☐ Drawings      Sheet(s)/Figs      to      ☐ Petition      pgs.  
☐ Assignment      pages & Recordation Cover Sheet ☐ Status Request  
☒ Trans. Ltr Nat'l Stage Entry (3pgs.) ☐ Trans. Nat'l Stage (2nd sub)  
☒ Information Disclosure Statement ☐ Resp. to Written Opinion  
☒ Form PTO-1449 1 pgs. ☐ Priority Document  
☒ Amendment ☐ Response 5 pages ☐ Notice of Appeal/Brief  
☐ Petition for Extension of Time ☐ Resp. to Rest. Req.      pgs.  
☐ Issue Fee Trans. (Part B) + 1 copy ☐ Req. to Correct Filing Receipt  
☐ Copy of Notice to File Missing Parts ☐ Copy of Filing Receipt  
☐ Request for Nonpublication (1 pg) ☐ Cert. of Correction (2)pgs.x2  
☐ Authorization to Charge Dep. Acct. # 19-2570 ☐ Postcard

DTOS Rec'd PCT/PTO 13 DEC 2004

Form PTO 1390 (REV 5-93)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER B45308	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED / ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5)	
INTERNATIONAL APPLICATION NO. PCT/EP03/006094		INTERNATIONAL FILING DATE 10 June 2003		PRIORITY DATE CLAIMED 13 June 2002	
TITLE OF INVENTION VACCINE COMPRISING MIXTURES OF MULTIVALENT MENINGOCOCCAL OUTER MEMBRANE VESICLES					
APPLICANT(S) FOR DO/EO/US Ramon F. BARBERA MORALES, Pierre M. DESMONS, Francisco J. DOMINGUEZ ALVAREZ, and Jan POOLMAN					

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ has been transmitted by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; and Form PTO-1449.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.  
(Add claim to priority via Preliminary Amendment for US originating cases only)
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☒ An Abstract on a separate sheet of paper.
18. ☒ Copy of Form PCT/ISA/210.
19. ☐ Other items or information.


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US APPLICATION NO. (if known) 37 CFR 1.50		INTERNATIONAL APPLICATION NO. PCT/EP03/006094		ATTORNEYS DOCKET NO. B45308	
20. [X] The following fees are submitted:				CALCULATIONS PTO USE ONLY	
Basic National Fee (37 C.F.R. 1.492(a)(1)-(5)):					
Search Report has been prepared by the EPO or JPO .....\$950.00					
International Preliminary Examination Fee paid to USPTO (37 CFR 1.492) .....\$750.00					
No International Preliminary Examination Fee paid to USPTO (37 CFR 1.492) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) .....\$790.00					
Neither International Preliminary Examination Fee (37 CFR 1.492) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....\$1,110.00					
International Preliminary Examination Fee paid to USPTO (37 CFR 1.492) and all claims satisfied provisions of PCT Article 33(2)-(4).....\$100.00					
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$950.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$0.00	
Claims	Number Filed	Number Extra	Rate		
Total claims	14 - 20 =	0	0 x \$18.00	\$0.00	
Independent claims	1- 3 =	0	0 x \$88.00	\$0.00	
Multiple dependent claims (if applicable)			+ \$300.00	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$950.00	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				\$	
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Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)) +				\$	
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- a. ☐ A check in the amount of \$\_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 19-2570 in the amount of \$950.00 to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-2570. A duplicate copy of this sheet is enclosed.
- d. ☒ General Authorization to charge any and all fees under 37 CFR 1.16 or 1.17, including petitions for extension of time relating to this application (37 CFR 1.136 (a)(3)).

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:  
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SIGNATURE  
James M. Kanagy  
NAME  
29,550  
REGISTRATION NO.

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PATENT  
ATTORNEY'S DOCKET NUMBER B45308TRANSMITTAL LETTER TO THE U.S. DESIGNATED OFFICE  
(DO/US) - ENTRY INTO NATIONAL STAGE UNDER 35 USC 371

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INTERNATIONAL APP. NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP03/006094	10 June 2003	13 June 2002

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TITLE OF INVENTION  
VACCINE COMPRISING MIXTURES OF MULTIVALENT MENINGOCOCCAL OUTER  
MEMBRANE VESICLES

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APPLICANT(S) FOR DO/US  
Ramon F. BARBERA MORALES, Pierre M. DESMONS, Francisco J. DOMINGUEZ  
ALVAREZ, and Jan POOLMAN

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Commissioner for Patents  
Mail Stop: PCT  
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## CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this Transmittal Letter, Form PTO 1390 and the papers indicated as being transmitted therewith, and Post Card are being deposited with the United States Postal Service on this date **13 December 2004** in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EV608165276US** addressed to the:

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Attorney Docket No. B45308

INTERNATIONAL APP. NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP03/006094	10 June 2003	13 June 2002

## TITLE OF INVENTION

VACCINE COMPRISING MIXTURES OF MULTIVALENT MENINGOCOCCAL OUTER  
MEMBRANE VESICLES

## APPLICANT(S) FOR DO/US

Ramon F. BARBERA MORALES, Pierre M. DESMONS, Francisco J. DOMINGUEZ  
ALVAREZ, and Jan POOLMANFILING OF AN INFORMATION DISCLOSURE STATEMENT

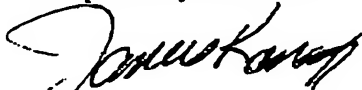
Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

☒ A copy of the International Search Report, which issued on International Application No. PCT/EP03/006094 is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.

☐ Copies of references not listed on the International Search Report are enclosed.

The attached list of citations on PTO Form 1449 is being submitted under the provisions of 37 CFR §1.56 and §1.97 in order to comply with the duty of disclosure. Their inclusion herein should not, however, be construed as an admission that any particular cited reference is effective prior art or that it discloses or renders obvious any aspect of the claimed invention. This statement is being filed within the time period specified in 37 CFR §1.97(b). No fee is required.

Respectfully submitted,

James M. Kanagy  
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13 DEC 2004

Sheet 1 of 1

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET NO. B45308	INTERNATIONAL APPLICATION NO. PCT/EP03/006094
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary)		APPLICANT Ramon F. BARBERA MORALES, Pierre M. DESMONS, Francisco J. DOMINGUEZ ALVAREZ, and Jan POOLMAN	
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## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
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## FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	WO 01/09350	8 Feb 04	WIPO				
	WO 02/09643	7 Feb 02	WIPO				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	DeKleijn et al., <i>Vaccine</i> , Vol. 18(15) pgs 1456-1466 (2000)
	Jodar et al., <i>Lancet</i> , Vol. 359 (9316) pgs 1499-1508 (2002)
	Milahres et al., <i>Infection and Immunity</i> , Vol. 66 (10) pgs 4755-4761 (1988)
	Pollard et al., <i>Archives of Disease in Childhood</i> , Vol. 87 (1) pgs 13-17 (2002)
	Sacchi et al., <i>Journal of Clinical Microbiology</i> , Vol. 39 (8) pgs 2897-2903 (2001)
	Tappero et al., <i>JAMA (Journal of the American Medical Association)</i> , Vol. 281 (16) pgs 1520-1527 (1999)
	Tondella et al., <i>Journal of Clinical Microbiology</i> , Vol. 38(9) pgs 3323-3328 (2000)
	Van Der Voort et al., <i>Vaccine</i> , Vol. 18 (14) pgs 1334-1343 (2000)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041 2042 2043 2044 2045 2046 2047 2048 2049 2050 2051 2052 2053 2054 2055 2056 2057 2058 2059 2060 2061 2062 2063 2064 2065 2066 2067 2068 2069 2070 2071 2072 2073 2074 2075 2076 2077 2078 2079 2080 2081 2082 2083 2084 2085 2086 2087 2088 2089 2090 2091 2092 2093 2094 2095 2096 2097 2098 2099 2100 2101 2102 2103 2104 2105 2106 2107 2108 2109 2110 2111 2112 2113 2114 2115 2116 2117 2118 2119 2120 2121 2122 2123 2124 2125 2126 2127 2128 2129 2130 2131 2132 2133 2134 2135 2136 2137 2138 2139 2140 2141 2142 2143 2144 2145 2146 2147 2148 2149 2150 2151 2152 2153 2154 2155 2156 2157 2158 2159 2160 2161 2162 2163 2164 2165 2166 2167 2168 2169 2170 2171 2172 2173 2174 2175 2176 2177 2178 2179 2180 2181 2182 2183 2184 2185 2186 2187 2188 2189 2190 2191 2192 2193 2194 2195 2196 2197 2198 2199 2200 2201 2202 2203 2204 2205 2206 2207 2208 2209 2210 2211 2212 2213 2214 2215 2216 2217 2218 2219 2220 2221 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2622 2623 2624 2625 2626 2627 2628 2629 2630 2631 26



## INTERNAL SEARCH REPORT

 International No.  
 PCT/EP/06094

 A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61K39/095

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

 Minimum documentation searched (classification system followed by classification symbols)  
 IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

BIOSIS, EPO-Internal, WPI Data, EMBASE, PAJ, CHEM ABS Data, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02 09643 A (GRANOFF DAN ;MOE GREGORY R (US); CHILDREN S HOSPITAL OAKLAND RE (U) 7 February 2002 (2002-02-07) cited in the application	1,12, 17-19
Y	claims 1,5,7,10,14-16,29 page 14, line 24 -page 15, line 12 page 18, line 31 -page 19, line 8 page 24, line 29-32 page 26, line 16-26 page 27, line 4-11 -& MOE-GR: "Differences in surface expression of NspA among Neisseria meningitidis group B strains" INFECTION AND IMMUNITY, vol. 67, no. 11, November 1999 (1999-11), pages 5664-5675, XP002266209 table 1	1-19

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

 "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
 "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

7 January 2004

Date of mailing of the international search report

04/02/2004

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## INTERNATIONAL SEARCH REPORT

PCT/EP 06094

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 01 09350 A (DALEMANS WILFRIED L J ;SMITHKLINE BEECHAM BIOLOG (BE); THIRY GEORG) 8 February 2001 (2001-02-08) cited in the application the whole document	1-19
Y	JODAR L ET AL: "Development of vaccines against meningococcal disease" LANCET, vol. 359, no. 9316, 27 April 2002 (2002-04-27), pages 1499-1508, XP004350750 ISSN: 0140-6736 abstract paragraph 'INTRODUCTION! page 1502, right-hand column, last paragraph -page 1504, right-hand column	1-19
A	TAPPERO JORDAN W ET AL: "Immunogenicity of 2 serogroup B outer-membrane protein meningococcal vaccines: A randomized controlled trial in Chile" JAMA (JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION), vol. 281, no. 16, 28 April 1999 (1999-04-28), pages 1520-1527, XP009022137 ISSN: 0098-7484 cited in the application the whole document	1-19
A	SACCHI CLAUDIO T ET AL: "Serosubtypes and PorA types of Neisseria meningitidis serogroup B isolated in Brazil during 1997-1998: Overview and implications for vaccine development" JOURNAL OF CLINICAL MICROBIOLOGY, vol. 39, no. 8, August 2001 (2001-08), pages 2897-2903, XP002263474 ISSN: 0095-1137 abstract	1-19
A	VAN DER VOORT EILEENE ROUPPE ET AL: "Immunogenicity studies with a genetically engineered hexavalent PorA and a wild-type meningococcal group B outer membrane vesicle vaccine in infant cynomolgus monkeys" VACCINE, vol. 18, no. 14, 31 January 2000 (2000-01-31), pages 1334-1343, XP002263475 ISSN: 0264-410X abstract	1-19
	--- -/--	

## INTERNATIONAL SEARCH REPORT

 Int. Classification No.  
 PCT/EP/05/06094

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>DE KLEIJN E D ET AL: "Immunogenicity and safety of a hexavalent meningococcal outer-membrane-vesicle vaccine in children of 2-3 and 7-8 years of age."            VACCINE. ENGLAND 14 FEB 2000, vol. 18, no. 15,            14 February 2000 (2000-02-14), pages 1456-1466, XP002263476            ISSN: 0264-410X            abstract</p>	1-19
A	<p>TONDELLA MARIA LUCIA C ET AL:            "Distribution of Neisseria meningitidis serogroup B serosubtypes and serotypes circulating in the United States"            JOURNAL OF CLINICAL MICROBIOLOGY, vol. 38, no. 9, September 2000 (2000-09), pages 3323-3328, XP002263477            ISSN: 0095-1137            abstract</p>	1-19
A	<p>MILAGRES LUCIMAR G ET AL: "Specificity of bactericidal antibody response to serogroup B meningococcal strains in Brazilian children after immunization with an outer membrane vaccine"            INFECTION AND IMMUNITY, vol. 66, no. 10, October 1998 (1998-10), pages 4755-4761, XP002263478            ISSN: 0019-9567            abstract</p>	1-19
A	<p>POLLARD A J ET AL: "The meningococcus tamed?"            ARCHIVES OF DISEASE IN CHILDHOOD, vol. 87, no. 1, July 2002 (2002-07), pages 13-17, XP002263479            ISSN: 0003-9888            the whole document</p>	1-19

## INTERNATIONAL SEARCH REPORT

Application No.  
EP 03/06094**Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
Although claim 18 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)**

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNAL SEARCH REPORT

Application No  
PCT/EP/06094

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0209643 A	07-02-2002	AU 8088301 A	13-02-2002
		BR 0112928 A	26-08-2003
		CA 2416137 A1	07-02-2002
		EP 1322328 A2	02-07-2003
		WO 0209643 A2	07-02-2002
		US 2002110569 A1	15-08-2002
WO 0109350 A	08-02-2001	AU 6833600 A	19-02-2001
		BR 0012974 A	07-05-2002
		CA 2380840 A1	08-02-2001
		CN 1377415 T	30-10-2002
		CZ 20020403 A3	15-05-2002
		WO 0109350 A2	08-02-2001
		EP 1208214 A2	29-05-2002
		HU 0203056 A2	28-12-2002
		JP 2003506049 T	18-02-2003
		NO 20020506 A	02-04-2002
		TR 200200275 T2	21-05-2002
		TR 200202448 T2	21-01-2003